

Remarks/Arguments:

Claims 23-40 are pending, with claims 23 and 35 being independent. Claims 24-34 are dependent (directly or indirectly) on claim 23, and claims 36-40 are dependent (directly or indirectly) on claim 35.

Claims 1-22 are cancelled, without prejudice or disclaimer.

Claim 23 is amended, above, in order to more clearly define the instant invention, as explained in connection with the § 112, ¶ 2, rejection (below).

Claims 24 and 25 are amended to expressly limit the "blood product" to "leukocytes" and "whole blood," respectively.

New, independent claim 35 contains the subject matter of present claim 23, but expressly recites—in the "determining" step—"whether leukocytes in the unit dose react with the substance in an immunofunctional, toxic, or modulatory blood reaction" (emphasis added).

Claims 23-34 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Reconsideration is requested.

According to the statement of rejection, claim 23 is allegedly indefinite for reciting "selecting a cryopreservative from among a plurality of identical cryopreserved doses . . . [and] it is unclear how selecting a cryopreservative relates to determining whether the unit dose reacts with the substance" (office action page 3). With all due respect, the statement of rejection is incorrect.

Contrary to the statement of rejection, rejected claim 23 does not recite "selecting a cryopreservative." Rejected claim 23 recites (emphasis added) "selecting a cryopreserved unit dose

of a blood product and a cryopreservative." In other words, the "blood product" and the "cryopreservative" are both components of the "cryopreserved unit dose" and, as such, of the "plurality of identical cryopreserved unit doses" from which the "cryopreserved unit dose" is selected.

Accordingly, the rejection is based on an incorrect interpretation of the rejected claim. Correctly interpreted, as explained above, rejected claim 23 is not indefinite i.e., the claim satisfies the requirements of § 112, ¶ 2. Notwithstanding the foregoing, and in a good faith effort to advance prosecution, claim 23 is currently amended.

Claim 23 is currently amended (as mentioned above) by rewriting "a cryopreserved unit dose of a blood product and a cryopreservative" to read "selecting a cryopreserved unit dose comprising a blood product and a cryopreservative." Thereby, the claim more clearly defines the "blood product" and the "cryopreservative" as components of, both, the "cryopreserved unit dose" and the "plurality of identical cryopreserved unit doses," from which the "cryopreserved unit dose" is selected.

For the foregoing reasons, the rejection of claims 23-34 under § 112, ¶ 2, is overcome. Withdrawal of the rejection appears to be in order.

Claims 23-34 were rejected under 35 USC 102(b) as allegedly anticipated by US5364756 (Livesey). Reconsideration is requested.

According to the statement of rejection (Office Action, page 4)"Livesey et al., teach the instant [rejected] claims" and, therefore (allegedly), the claims are properly rejected under § 102 (b). With all due respect, the statement of rejection is mistaken.

For anticipation under §102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

Livesey neither teaches nor suggests the method-step limitation on all the rejected claims (*emphasis added*)

determining . . . whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction.

The statement of rejection apparently relies on the teachings of Livesey in which "erythrocyte samples were . . . assessed for morphology using phase contrast microscopy" (Office Action, page 4) to meet the aforesaid method-step limitation on the rejected claims. As readily appreciated, the reliance is misplaced.

Livesey's assessing the rehydration-substance-containing erythrocyte samples for morphology, using phase contrast microscopy, determines neither (1) whether the erythrocyte "reacts with" the substance nor (2) whether there is "an immunofunctional, toxic, or modulatory blood reaction" (between the erythrocyte and the substance), i.e., as opposed to what occurs as recited in the determining-step limitation on the rejected claims. The "absence from Livesey of the determining step limitation "negates anticipation" of the rejected claims. *Kolster Speedsteel AB*, 230 USPQ at 84.

Moreover, presently rejected claims 24, 25, 27, and 30-34 are independently novel over Livesey, under §102(b). Livesey neither teaches nor suggests the presently claimed "method" limited to "wherein the blood product is leukocytes" and "wherein the blood product is whole blood," as provided in rejected claims 24, 25, 27, and 30-34. As such, the "absence" from Livesey of the aforesaid leukocytes and whole blood limitations independently "negates anticipation" of present claims 24, 25, 27, and 30-34. *Kolster Speedsteel AB*, 230 USPQ at 84.

For the forgoing reasons, the rejection of claims under §102(b) is overcome. Withdrawal of the rejection appears to be in order.

Claims 23-34 were rejected under 35 USC 103(a) as allegedly unpatentable over US5364756 (Hill) in view of Livesey. Reconsideration is requested.

The statement of rejection apparently alleges that (1) Hill teaches the "contacting" and "determining" steps—allegedly using whole blood—recited in the rejected claims and (2) Livesey teaches the "selecting" and "thawing" steps recited in the rejected claims. According to the

statement of rejection it would have allegedly been obvious to combine the teachings of Hill and Livesey such that the selecting and thawing steps (allegedly taught by Livesey) are combined with the contacting and determining steps (allegedly taught by Hill); and, thereby, Hill plus Livesey (allegedly) fully meet the selecting, thawing, contacting, and determining steps as recited in the rejected claims. The allegations set forth in the statement of rejection are not well taken.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002). When a reference is relied on to meet limitations on a claim, in a rejection under §103(a) based on combined prior art teachings, "individual defects of the reference . . . can defeat the rejection." *In re Lyons*, 150 USPQ 741, 746 (CCPA 1966). *Ryko Manufacturing Co. v. NuStar, Inc.*, 21 USPQ2d 1053 (Fed. Cir. 1991).

Incorrect reliance on Livesey is discussed above.

Hill is directed to preparing a "control sample [that] comprises a lyophilized mixture comprising fixed red blood cells and heparinized plasma solids" (Abstract) "specifically designed for . . . prothrombin time measuring" (column 5, lines 48-55). According to Hill (emphasis added):

The plasma sample can be modified before the red blood cells are added to produce the whole blood control sample. Typical modifications are pooling of plasmas from different donors in order to provide a large number of control samples having the same biochemical characteristics, heating or otherwise treating in order to destroy at least a portion of the coagulation factors (thereby reducing the rate of coagulation) Typical treatments used to destroy coagulation factors include solid-phase adsorption of factors with barium sulfate, aluminum hydroxide, asbestos, and/or antibodies [column 4, lines 35-46].

"The plasma, either treated or untreated, is mixed with fixed red blood cells to form a suspension" (column 4, lines 61-62). The control "[s]amples are withdrawn from the uniformly blended suspension and quick-frozen" (column 5, lines 13-15). "After quick-freezing, the samples are lyophilized" (column 5, line 32).

The above referenced teachings of the reference show that any modification according to Hill effects only the "plasma" component—of the "control sample" invention—and it occurs prior to control-sample lyophilization. On the contrary, as opposed to Hill, the presently claimed invention requires "selecting" a previously lyophilized (i.e., "cryopreserved") blood product, "thawing" the blood product, and, only then, "determining" whether "an immunofunctional, toxic, or modulatory blood reaction" has occurred. As such, the rejection mistakenly relies on Hill to meet limitations on the rejected claims, which renders the rejection untenable. *Lyons*, 150 USPQ at 746. *Ryko Manufacturing Co.*, *supra*.

Moreover, Livesey provides no teaching or suggestion to supply the aforesaid deficiencies in Hall. For example (as explained above), Livesey fails to teach or suggest the determining-step limitation on the rejected claims, which is absent from Hall. When "the cited references do not support each limitation of [the] claim," a rejection under § 103(a) is "inadequate on its face." *Thrifty*,

63 USPQ2d at 2008. "All words in a claim must be considered in judging the patentability of that claim against the prior art," *Wilson*, 165 USPQ at 496, "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Murphy*, 217 USPQ at 481.

Still further, presently rejected claims 24, 25, 27, and 30-34 are independently patentable, under §103(a), over the combined teachings of Hill and Livesey. As explained above, Livesey neither teaches nor suggests the presently claimed "method" limited to "wherein the blood product is leukocytes" and "wherein the blood product is whole blood," as provided in rejected claims 24, 25, 27, and 30-34. The same applies to Hill. Since "the cited references do not support each limitation of [the] claim," the rejection of claims 24, 25, 27, and 30-34 under §103(a) is "inadequate on its face," *Thrift*, 63 USPQ2d at 2008, independently of all the rejected claims.

To the extent that the rejection relies on Hill's "whole blood control sample" to meet the "whole blood" limitation on the present claims, the reliance is misplaced. While Hill may use the term *whole blood*, the "whole blood control sample" neither teaches nor suggests the "whole blood"—as "blood product . . . obtained from a single or pooled sample of blood taken from a human or animal" (*emphasis added*)—limitation on the present claims. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *Wilson*, 165 USPQ at 496. On the contrary, Hill's "blood control sample comprises" separated "heparinized plasma solids" recombined with "red blood cells." The totality of each reference's teachings must be considered when combining those teachings with the rest of the prior art. *W. L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

For the forgoing reasons, the rejection of claims under §103(a) is overcome. Withdrawal of the rejection appears to be in order.

Favorable action is requested.

Respectfully submitted,

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